

REMARKS

Applicants submit this Amendment in reply to the Office Action dated September 17, 2003. In this Amendment, Applicants cancel claims 58 and 66, without prejudice or disclaimer, and amend claims 11, 45, 59, and 67. Applicants also amend Fig. 1 to correct an inadvertent typographical error, and present new Fig. 3a for the reasons set forth in the following remarks. Before entry of this Amendment, claims 11, 45, and 47-68 were pending in this application. After entry of this Amendment, claims 11, 45, 47-57, 59-65, 67, and 68 are still pending in this application.

In the Office Action, the Examiner objected to the drawings, specification, and claims 58 and 66; rejected claims 11, 45, and 47-86 under 35 U.S.C. § 112, second paragraph; rejected claims 11, 45, 48, 50-55, and 61-63 as being unpatentable over U.S. Patent No. 5,306,294 to Winston et al. ("Winston") in view of U.S. Patent Application Publication No. 2001/0034549 A1 to Bartholf et al. ("Bartholf"); rejected claims 47 and 49 under 35 U.S.C. § 103(a) as being unpatentable over Winston et al. in view of Bartholf, and further in view of U.S. Patent No. 5,810,837 to Hofmann et al. ("Hofmann"); rejected claims 56-60 and 64-68 under 35 U.S.C. § 103(a) as being unpatentable over Winston et al. in view of Bartholf, and further in view of U.S. Patent No. 5,100,381 to Burns. Applicants respectfully respond to these rejections as set forth in the following remarks.

With regard to the drawing objection, Applicants add new Fig. 3a to show that "the non-braided translucent region has a length that substantially coincides with a constrained length of a stent within the outer tubular structure." New Fig. 3a is the outer assembly 105 of Fig. 3 with a stent 102 disposed under the distal region 105a.

Applicants have also amended the specification to refer to new Fig. 3a. The originally

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

filed specification, drawings, and claims support these drawing changes. Specifically, the subject matter of new Fig. 3a is supported at least, for example, by originally filed Figs. 2a and 3, and originally filed claims 11 and 45. No new matter was introduced. Accordingly, Applicants respectfully request withdrawal of the drawing objection.

With regard to the objection to the specification, Applicants amend the specification as set forth above to clarify that a distal region of the outer tubular structure may be "clear and/or translucent," and also to recite that "the non-braided translucent region may have a length that substantially coincides with a constrained length of a stent within the outer tubular structure." Once again, the originally filed specification, drawings, and claims support these changes, and no new matter is being added. Accordingly, Applicants respectfully request withdrawal of the objection to the specification.

With regard to the objection to claims 58 and 66, although Applicants do not necessarily agree that claims 58 and 66 do not further limit the subject matter of claims 57 and 65 respectively, solely in the interests of expediting the prosecution of this application, Applicants have cancelled claims 58 and 66. Accordingly, Applicants respectfully request withdrawal of the objection to claims 58 and 66. The cancellation of claims 58 and 66 necessitated the changes in dependency of claims 59 and 67.

Applicants respectfully traverse the rejection under §112, second paragraph. In the rejection, the Examiner argues that "[c]laim 11 is confusing and inaccurate since the distal end of the inner elongate structure (at 117) does not substantially coincide with the distal end of the outer tubular structure 105 since tip 117 extends distally beyond the distal end of outer tubular structure 105 as shown in figure 5b." In response, lead point

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

117 may be an additional structure of the delivery system 100. (See paragraph 34 of the specification.) As such, point 117 may not necessarily be considered a part of inner assembly 104. For such a case, and as shown in Fig. 5b, the distal end of the inner elongate structure 104 does substantially coincide with the distal end of the outer tubular structure 105. Furthermore, even if the lead point 117 is considered the distal end of the inner elongate structure, the claims are still not indefinite as the lead point 117 does substantially coincide with the distal end of the outer tubular structure 105. In addition, the term "substantially" leaves flexibility and implies something less than absolute coincidence between the ends of the structures.

With regard to the rejection of claim 61 for allegedly indefiniteness, Applicants assert that claims 11 and 61 do not recite the same claim element. Applicants have amended claim 11 to make that even more clear. Claim 11 recites a system having "an outer tubular structure having a proximal end and a distal end, wherein the outer tubular structure has a non-braided translucent region at its distal end and the non-braided translucent region has a length that substantially coincides with a constrained length of a stent to be placed within the outer tubular structure." Claim 61 recites a system "further comprising a stent located in the stent accommodating area and within the outer tubular structure when the stent is constrained." Claim 11 does not positively recite a stent, while claim 61 does positively recite a stent. Thus, claims 11 and 61 do not recite the same claim element. Accordingly, Applicants respectfully request withdrawal of the §112, second paragraph, rejection.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
www.finnegan.com

With regard to the rejections of all the claims under 35 U.S.C. §103(a), none of Winston, Bartholf, Hofmann, or Burns, either individually or in combination, recite every aspect of the claimed invention.

For example, independent claims 11 and 45 each recite “an outer tubular structure having a proximal end and a distal end, wherein the outer tubular structure has a non-braided translucent region at its distal end and the non-braided translucent region has a length that substantially coincides with a constrained length of a stent within the outer tubular structure.” The amendments to claims 11 and 45 are supported at least, for example, by Figs. 3 and 5a, page 13, lines 20-23, page 14, lines 17-19, and page 16, lines 20-23 of the specification. No new matter was introduced. None of the cited references recite at least this aspect of the claimed invention. The Examiner recites on page 4 of the Office Action that “[t]he Bartholf et al. distal region of the outer tubular structure is ‘translucent’ as claimed since the stainless steel braiding 70 and teflon layer 69 diffuse the light to some extent.” Thus, by the Examiner's own admission, Bartholf does not disclose a “non-braided translucent region,” and none of the other cited references remedy this deficiency.

Instead, Bartholf discloses that enlarged distal section 44 “is formed of an inner teflon layer 69 having stainless steel braiding 70 disposed on the teflon layer 69, and a top coat 72 bonded to the stainless steel braiding 70.” (Paragraph [0034]). Bartholf discloses that the top coat 72 may be formed of a clear material. Bartholf further discloses that the only purposes of a clear top coat are to inspect the implantable stent prior to inserting the catheter in the body, for example during manufacture or a by a physician prior to delivery. (Paragraphs [0017], [0019], [0020], [0034], and [0037]). In

contrast, and as explained in Applicants' specification, a non-braided translucent region allows a health care worker to observe the relative movement of the stent during deployment such that the stent is deployed in a suitable area. For example, a non-braided translucent region may allow the proximal end of the stent to be visible to the health care worker as the proximal end passes within the clear region before stent release. As another example, a non-braided translucent region permits visual, radiopaque signal bands to become visible through a fluoroscope through the clear portion of the exterior tube such that a health care worker would be signaled that the stent is close to being deployed. (Page 15, lines 5-9; page 16, lines 14-19).

Accordingly, there are advantages to having a non-braided translucent region.

Claims 47-57, 59-65, 67, and 68 depend from one of independent claims 11 and 45, and are therefore allowable for at least the same reasons that each of those respective independent claims is allowable. In addition, at least some of the dependent claims recite unique combinations that are neither taught nor suggested by Winston, Bartholf, Hofmann, Burns, or other cited art, and therefore are separately patentable.

In view of the foregoing remarks, the claimed invention is neither anticipated nor rendered obvious in view of the prior art references cited against this application.

Applicants therefore request the entry of this Amendment, the Examiner's reconsideration of the application, and the timely allowance of the pending claims.

The Office Action contains characterizations of the claims and the related art with which Applicants do not necessarily agree. Unless expressly noted otherwise, Applicants decline to subscribe to any statement or characterization in the Office Action.

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
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Fax 202.408.4400
www.finnegan.com

In discussing the specification, claims, abstract, and drawings in this Amendment, it is to be understood that Applicants are in no way intending to limit the scope of the claims to any exemplary embodiments described in the specification or abstract and/or shown in the drawings. Rather, Applicants are entitled to have the claims interpreted broadly, to the maximum extent permitted by statute, regulation, and applicable case law.

Please grant any extensions of time required to enter this response and charge any additional required fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

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By: 

Michael W. Kim
Reg. No. 51,880

Attachments: Formal Replacement Sheets including Figs. 1, 3, and 3a
Annotated Sheet Showing Changes to Fig. 1

FINNEGAN
HENDERSON
FARABOW
GARRETT &
DUNNER LLP

1300 I Street, NW
Washington, DC 20005
202.408.4000
Fax 202.408.4400
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